UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,831	03/09/2006	Hans-Ulrich Petereit	267336US0PCT	8866

22850 7590 02/22/2010

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/532,831	PETEREIT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1 - 3, 8, 9, 13, 14 and 16 are rejected under 35 USC 103(a) as being unpatentable over Ulmius et al. (US 5,643,602) in view of Beckert et al. (WO 01/68058). Applicants argue there is no direction to select the claimed metarial, contrary to the assertion of the previous Office Action there is sufficient evidence of unexpected results, theres is no reasonable prediction of success for the percentage release of active agent and there is no support for the exclusion of the various excipients.

These arguments are unpersuasive. Ulmius et al. includes the EUDRAGIT® NE in aquesous diseprsion (what the '30D' part of the name refers to) among a limited number of preferred polymers and based on Applicant's arguments, it appears that this polymer is the ingredient which provides the independence of the release rate from the osmotic/ionic conditions of the medium. The teachings of the reference aren't limited to the examples. The exmamples given by Applicant to support the unexpected percentage release rate all relate to a very limited number of active ingredients (all but one relate to budesonide) and there is insiufficient evidence that the observed independence of release rate from the osmotic conditions applies to all active ingrdients, which the breadth of the claims in regards to the active ingredient. The perecentage release flows from the comopsition and structure of the dosage form, and there is a reasonable expectation of success in preparing the dosage form, which will lead to the release profile. In regards to the excipients, Ulmius discloses that they are optional, which means that these ingredients are not required and thus can be excluded from the composition(s).

Claims 1 - 3, 8, 9, 13, 14 and 16 are rejected nder 35 USC 103(a) as being unpatentable over Ulmius et al. (US 5,643,602) in view of Gang et al. (Proc of the 7th SECJ, 2001). Applicants response is slightly confusing as to this rejection as a p 7 of the response indicates that Beckert is the primary reference, but then references Ulmius on p 8. As no rejection with Beckert as the primary refrence has been made, the Examiner will assume that the primary reference being argued was Ulmius.

Applicants argue that the active in Gang is in the pellet core and not bound to the inner coating layer, which leads to different release curves and again that the observed relese profile is unexpected.

These arguments are unpersuasive. The location of the active ingredient comes from the teachings of the primary reference (Ulmius). The arguments regarding the unexpected release profile were discussed above.